MAR - 1 2001

K010285

Special 510K Summary Statement for the Sciton Inc Profile Laser

1. General Information

Submitter:	Sciton Inc 845 Commercial Street Palo Alto, CA 94303
Contact Person	Peter Allen
Summary Preparation Date	February 26, 2001,

2. Names

Device Names	Contour Profile
Primary Classification Names:	Laser Powered Surgical Instrument for use in Plastic Surgery and Dermatolgy in accordance with 21CFR 879-4810.79-GEX

3. Predicated Devices

The product specifications, functionality, indications for use, and treatment parameters of the Sciton Inc, Contour Profile Laser are the same as the combined legally market lasers:

Sciton Inc – Erbium 2000

Sciton Inc - Image Laser

4. Product Description

The Sciton Inc,Contour Profile Laser is a modification to combine two lasers into one chassis with a commom beam path. The unmodified devices are Erbium 2000 Laser, with ScanTech Scanner and Image Longpulse Nd:YAG

Two pairs of laser heads are shared by a common power supply and control system. The internal computer can be directed to select either the two Erbium heads (Erbium 2000) or the two Nd:YAG heads (Image). When the laser is first turned on the physician is able to select the desired wavelength via the Control Panel. The Physician is then requested to confirm the wavelength selection and promted by the computer as to the correct wavelength of glasses to be used. (Safety Glasses are provided that provide protection against both wavelengths)

The Erbium 2000 laser is intended to be used to deliver Erbium light energy (wavelength 2940 nm) for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in a variety of medical specialties.

Image is a long pulsed, solid state infrared laser. It is intended to deliver laser energy for use in surgical and aesthetic applications requiring the long term reduction of Hair Folicles. It is also intended to provide coagulation and hemostasis. The Image Laser produces a beam of infrared light at a wavelength of 1064nm.

The system consists of:

A laser console
- Comprising two Erbium Laser Heads
- And two Nd:YAG Heads
- A common Power Supply

Internal computer
Control panel and display

Articulated Arm
Footswitch with optional handswitch
Scanner and Handpieces with cooling capability

5. Indications for Use

The Sciton Inc Contour Profile Laser is designed for use in surgical applications requiring the excision, incision, ablation, vaporization and coagulation of soft tissue, and for skin resurfacing. Soft tissue includes

skin, subcutaneous tissue, striated and smooth tissue, muscle, cartilage, cartilage meniscus, calculi or fragments, mucous membrane, lymph vessels and nodes, organs and glands. Surgical specialties and applications include: general surgery, plastic surgery, aesthetic surgery, dermatology, urology, gynecology, genitourinary, ENT, pulmonary surgery, thoracic surgery, podiatry, oral& maxillofacial surgery, ophthamology (including oculoplasty), small and large joint arthroscopy, microdiscectomies, and endoscopic procedures.

It is also intended for use in surgical and aesthetic applications
for the removal of unwanted hair and is indicated for use on Fitzpatrick skin type I-VI and for the treatment of vascular lesions in general, plastic surgery and dermatology on Fitzpatrick skin types I-VI..

6. Rationale for Substantial Equivalence

The Sciton Inc Profile Laser shares the same indications for use, same design features (including wavelength, active medium, cooling system and controls), same functional features as the two combined predicate devices. Therefore the Sciton Inc Contour Profile Laser is substantially equivalent to the Sciton Inc Erbium 2000 and Image Laser.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Peter N. Allen
Director, Regulatory Affairs
Sciton, Inc.
845 Commercial Avenue
Palo Alto, California 94303

Re: K010285
Trade Name: Contour Profile Laser
Regulatory Class: II
Product Code: GEX
Dated: January 30, 2001
Received: January 31, 2001

Dear Mr. Allen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Miriam C. Provost
Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FDA Submission Cover Sheet

510(K) Number (if known): K010285

Device Name: **Contour Profile Laser**

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use _____
(Per 21CFR 801)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010285